SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING
CLINICAL TRIALS NETWORK

SNMMI CLINICAL TRIALS NETWORK

Committee Report
SNMMI Board of Directors
June 2015

Highlights:

- The Clinical Trials Network (CTN) continues to work on 7 different investigational agents being used in trials or in drug development projects. These include FLT, DOTATATE, DOTATOC, FDHT, F-Choline, Fluciclovine, and HX-4.
- The 3rd Theranostics World Congress on ^{68}Ga and PRRT was very successful with over 200 registrants and 15 exhibitors and sponsors. Every lecture from the three-day congress was recorded and is available online at https://vimeo.com/channels/3wtc. The abstracts were published in a supplement to JNM (May). The meeting was revenue positive.
- Efforts by the Gallium Users Group to facilitate approval of ^{68}Ga-labelled somatostatin receptor agents in the US have resulted in increased use of these agents in investigational studies. There are currently 12 active sites with an IND and 5 additional sites pending IND approval. A number of these groups used the ^{68}Ga-DOTA-XXX template documents developed by the Gallium Users Group and available on the CTN website in their applications to the FDA.

Current projects of the CTN include:

- Dr. John Sunderland (Chair, Database Committee) submitted a grant application to the NIH in response to a request for academic/industry partnerships on to accelerate the translation of clinical in vivo imaging systems and/or methods that are designed to solve a targeted cancer problem. The CTN plays in integral role in this project if it is funded. The decision is expected in early June 2015.
- Additional papers are planned based upon the results of the CTN chest phantom scanner validations. An abstract on phantom failure occurrences will be presented at the SNMMI 2015 annual meeting, and a paper on CT dosimetry was submitted to JNM this month.
- The upgraded Database Reporting Tool (DaRT) rolled out its upgraded version that links directly to the new CTN Database. Both tools have enhanced search functions and reporting capabilities, and the database has the ability to perform a more detailed analysis of the collected data, including scanner validation results. A complete data refresh is underway. Additionally, new sites outside of the US are being added, especially manufacturing sites. This information is being used by the Global Initiative.
- The Radiopharmaceutical Manufacturers Committee plans to conduct both on-site and desktop audits of the PET production sites manufacturing FLT for the ongoing BMS study that cross-references the SNMMI-held FLT IND.
- CTN continues to provide support for the 5-year NIH R01 grant on harmonizing PET reconstructions for cancer clinical trials. Staff assists academic centers with phantom scanning, oversees image upload and management in the Keosys Imagys server and provides general administrative report. Investigators will submit for the grant's fourth year of funding.

- Members of the SPECT Committee are concentrating efforts to develop parameters and guidelines for data collection and analysis for validating cardiac SPECT phantoms. A list of SOPs for the Committee was drafted, with priority assigned to personnel training and image review.
- As part of its ongoing collaboration with EANM/EARL, CTN hopes to finalize harmonizing specific areas of these two scanner validation programs in an effort to standardize PET imaging on a more global front.

CTN continues to investigate ways to collaborate with other groups and industry partners on projects that benefit the entire molecular imaging community. Funding will be sought to support expansion of its Educational Program to include higher level, scientific offerings developed by experts in the field. CTN has been asked by the NCI Imaging Program, namely Paula Jacobs, to build a tool for connecting IND holders of PET drugs with potential would-be investigators. This site would eventually house INDs and other regulatory documents for ease of sharing and collaboration.